



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License, Inter-Institutional Agreement-Institution

Lead: Multivalent Vaccines for Rabies Virus and Coronaviruses

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Thomas Jefferson University, located in Philadelphia, Pennsylvania to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Wade Green, PhD, Lead Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases (NIAID), 5601 Fishers Lane, Suite 6D, MSC9804, Rockville, MD 20852-9804, phone number 301-761-7505, or wade.green@nih.gov.

SUPPLEMENTARY INFORMATION:

The following represents the intellectual property to be licensed under the prospective agreement: US Provisional Patent Application Number 62/318,087, filed 04 April 2016, titled “Multivalent vaccines for rabies virus and coronaviruses” (HHS

Reference No. E-128-2016-0-US-01); PCT Application Number PCT/US17/25623, filed 31 March 2017, titled “Multivalent vaccines for rabies virus and coronaviruses” (HHS Reference No. E-128-2016-0-PCT-02); US Patent 11,041,170, issued 22 June 2021, titled “Multivalent vaccines for rabies virus and coronaviruses” (HHS Reference No. E-128-2016-0-US-05); US Patent Application Number 17/307,066, filed 04 May 2021, titled “Multivalent vaccines for rabies virus and coronaviruses” (HHS Reference No. E-128-2016-0-US-06); EPO Patent Application Number 2017718216.9, filed 31 March 2017, titled “Multivalent vaccines for rabies virus and coronaviruses” (HHS Reference No. E-128-2016-0-EP-03); and Saudi Arabian Patent Application Number 518400172, filed 04 October 2018, titled “Multivalent vaccines for rabies virus and coronaviruses” (HHS Reference No. E-128-2016-0-SA-04). All rights in these inventions have been assigned to Thomas Jefferson University, University of Maryland, Baltimore, and the Government of the United States of America as represented by the Secretary, Department of Health & Human Services.

The prospective patent license will be for the purpose of consolidating the patent rights to Thomas Jefferson University, one of the co-owners of said rights, for commercial development and marketing.

Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200–212.

The prospective interinstitutional agreement will include an exclusive license for NIAID’s rights in these jointly owned patents. It will be sublicensable, and any sublicenses granted by Thomas Jefferson University will be subject to the provisions of 37 CFR part 401 and 404.

The subject patent rights are related to novel recombinant vaccine constructs based on a genetically modified, attenuated rabies virus vaccine vector expressing one or more

coronavirus immunogenic polypeptides. These constructs elicit strong bi-valent immunogenic responses against both rabies virus and the respective coronavirus in animal models. The novel rabies virus vector used in these constructs was developed by Thomas Jefferson University prior to the co-development of the subject patent rights by Thomas Jefferson University, the University of Maryland, Baltimore, and NIAID.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

Complete license applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under *the Freedom of Information Act*, 5 U.S.C. 552.

Dated: August 5, 2022.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.